



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,556	09/23/2005	Harald Groger	7601/84378	1889
66991 7590 07/09/2008 LAW OFFICE OF MICHAEL A. SANZO, LLC 15400 CALHOUN DR. SUITE 125 ROCKVILLE, MD 20855				
EXAMINER KOSAR, AARON J				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
07/09/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/550,556

**Applicant(s)**

GROGER ET AL.

**Examiner**

AARON J. KOSAR

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendments*

Applicant's amendment and argument filed February 13, 2008 in response to the non-final rejection, are acknowledged and have been fully considered.

Applicant has amended the claims by canceling the previously pending claims, rendering the previous rejections moot. Applicant has canceled claims 15-36, and introduced new claims 37-56. Claims 37-56 are pending and have been examined on the merits.

### *Specification*

The disclosure is objected to because of the following informalities:

In Example 6 (for example, page 17, lines 6 and 7), the compound  $\alpha$ ,*meta*-dichloroacetophenone / 2',3-dichloroacetophenone appears to be a typographical/nomenclature variants of the compound 2,3'-dichloroacetophenone (*cf.* CAS REGISTRY "2,3'-Dichloroacetophenone [21886-56-6]" and "2-Chloroacetophenone [532-27-4]", accessed 1 July 2008, 3 pages.).

Example 7 (page 17, lines 25 and 26) appears to inadvertently refer to *the aldehyde*, cinnamaldehyde, as *the ketone*.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 37-56** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "higher than or equal to *its solubility limit*" in claims 37 is a relative term which renders the claim indefinite. The term "solubility limit" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Furthermore, the claims do not limit the solubility limit to any particular solvent, temperature, etc. and thus it is also unclear whether the concentration of the substrate and the solubility limit refer to the same sample (or substrate-solvent pairing) or if the solubility is a reference solubility measurement but not required by the solution/suspension in which transforming of the organic compound is performed (e.g. measuring the water solubility and then using this value for reactions in DMSO (or other solvent)). Furthermore, the term "concentration", expressed as molarity (M), is understood in the art to refer to moles of a substance per volume solution. Accordingly sample which is in the solid phase and not dissolved does not contribute to the concentration, thus it is unclear how a concentration can exceed the solubility limit, rendering the claims indefinite.

However, this ground of rejection may be overcome, for example, by reciting a relative solubility limit providing a nexus between the composition and the solvent in which the solubility limit is measured (e.g. "...or equal to *said organic compound's solubility limit in said solvent system*") rather than an absolute solubility limit (solubility limit *per se*).

In claims 48 and 53, the phrase “isolated from the organic phase” is indefinite. The phrase is indefinite because the phrase is unclear with respect to the fraction containing the product. The claim recites that the reaction mixture is (1) separated into an organic and aqueous phase and (2) the product is isolated *from* the organic phase. It is unclear if the product is isolated *from* the organic solvent and *in* the aqueous phase or, in the alternative, if the product is isolated *in* the organic solvent and then further isolated *from* said organic solvent. Each is a reasonable interpretation of the claims; however, each embraces different subject matter such that one would not be able to determine the metes and bounds of the claims, thereby rendering the claims indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 37-56** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107

Art Unit: 1651

F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.” MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...”) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitutes a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*.

In the instant case, the claims are drawn to a method of making an oxidized or reduced alcohol, aldehyde, or ketone.

*(1) Level of skill and knowledge in the art:*

The level of skill in the art is high such that one of skill would recognize enzyme substrate interactions and the role of cofactors. However, the myriad of components (i.e. enzymes, cofactors, and respective products) and the myriad of conditions that modulate or influence the genus of oxidation-reduction (redox) reactions embraced by the instant claims is beyond the knowledge of one of skill in the art.

*(2) Partial structure, (3) Physical and/or chemical properties, and (4) Functional characteristics:*

The method is disclosed as having various components; however, the active steps and the products produced are not structurally described (e.g. “desired product”), limited, or defined by the claimed invention. The claims also include an exponentially larger breadth of components, reactions, and products than is supported by the specification or than is disclosed in the examples/specification.

*(5) Method of making the claimed invention:*

The result of the method is not claimed in a manner such that a nexus between the claimed method and the methods of the preferred embodiments/specification is not established.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 37 is a broad generic, with respect to all possible compounds (reagents, products, enzymes, cofactors, solvents, etc) encompassed by the claims. The possible structural variations among the compounds/components are limitless to *any* class of compound(s), redox transformation, and method.

It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP § 2163. Here, though the claims may recite some functional characteristics (e.g reducing, oxidizing, cofactor, cofactor dependence, desired product, etc.), the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lacks a sufficient variety of species to reflect



this variance in the genus since the specification does not provide any examples of derivatives. While having written description of various species and combinations thereof - including the disclosed species of aqueous/water-containing solvents; the species of organic compound: cinnamaldehyde, 2- or 4-chloroacetophenone, and 2,3'-dichloroacetophenone; the reduction of said species of organic compound; the species of cofactor: NAD(P)H; the species of enzyme: formate dehydrogenase (FDH) and an enantioselective alcohol dehydrogenase ((S)-ADH) - the specification lacks sufficient variety of species to be representative of all methods in all instances involving the breadth of the claimed compounds/enzymes/cofactors, chemical transformations, and desired products.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

**Claims 37-56** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 15-24 and 35-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reacting a subset of aldehydes and ketones (see examples) in the manner of the embodiments, does not reasonably provide enablement for all enzymatic reactions in all instances as embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to a redox reaction of an alcohol, aldehyde, or ketone to produce a desired product; however, the disclosed invention is drawn to a narrower breadth, including methods of reducing cinnamaldehyde (an aldehyde) or acetophenones (ketones), to alcohols or of oxidizing alcohols to aldehydes or ketones. Thus, the claims taken together with the specification imply a breadth of claims greater than that which is supported by the specification.

*(3) The state of the prior art, (4) the predictability or unpredictability of the art, (5) the relative skill of those in the art:*

The state of the prior art is such that one of skill would not be apprised as to the full scope of enzymatic reactions/transformations, substrates/compounds/cofactors, or reactions commensurate with the claims.

Although the relative skill of those in the art is high, since the *a priori* determination of all possible enzymatic redox reactions, all possible cofactors, and all possible redox products of functionalized reactants (alcohol-, aldehyde- ketone-containing compounds) arising from the method, as claimed, is beyond the ordinary skill of one in the art and/or largely unsolved, means for determining the products/result of practicing the invention is highly unpredictable.

*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided examples of a subset of reactants and procedures for reacting those compositions. The specification has provided working examples of contacting acetophenones (2'-dichloro acetophenone or 2- or 4-chloroacetophenone) and cinnamaldehyde.

However, the specification does not provide direction or a sufficient number of working examples sufficient to describe the species/genera of an aldehyde/ketone/alcohol capable of enzymatic reduction and/or oxidation reactions; cofactors or enzymes/cofactor-dependent enzymes capable of being regenerated/regenerating; or the myriad of desired products resulting from the myriad of possible component and reaction combinations, beyond the extent of the reagents, products, enzymes, and reactions recited in the working examples.

*(8) The quantity of experimentation necessary:*

Considering the state of the art and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make and use the invention as claimed.

It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 37-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over BOMANNUS (US 2003/0054520 A1) or YAMAMOTO (US 2002/0064847 A1) or SJOBERG (US 6,500,661) or ORLICH (9:PTO-1449 3/20/2007) or GROGER (4:PTO-1449 3/20/2007).

To the extent that the claims teach a method of reacting an organic compound with an enzyme and regenerating a co-factor, the claims stand as obvious over the prior art.

BOMANNUS teaches a method of enantioselectively transforming an organic compound, including organic compounds, including alcohols and carbonyl-containing compounds, including ketones; enzymes, including alcohol dehydrogenase; and co-factors, including NADH or NADPH (claims; ¶ [0043],[0044],[0094];table, example 4). Bomannus also teaches ADH reduction of a ketone to yield an alcohol (e.g. claims 22-31; ¶ [0098]) or oxidizing an alcohol (claims 32-41). Additionally, Bomannus teaches aqueous solvent by teaching pH of the compositions (e.g. ¶ [0090]).

YAMAMOTO teaches a method of transforming an organic compound, including the organic compounds, reduced or oxidized by a cofactor-dependent enzyme (e.g., table 1); enzymes, including (secondary) alcohol dehydrogenase; and co-factors, including NAD(P)H/NAD(P)<sup>+</sup> (¶ [0046]; claims; table 1). Yamamoto constructively teaches an aqueous solvent system by teaching pH optima in the reaction. Furthermore, Yamamoto teaches that the concentration of the substrates of 5-100mM (table 1) and reacting in 55°C (examples 3 and 5).

SJOBERG teaches an enzymatic reaction comprising transformation of glucose to gluconate via an enzyme coupled to enzymatic NAD(P)/NAD(P)H recycling enzyme reaction system (e.g. figure 16). SJOBERG also teaches 1mM and 65 mM substrate concentrations, including dilution with water to a desired volume (e.g. column 30, ¶5; column 36, ¶ 3).

ORLICH teaches batch reacting FDH; ADH; NAD<sup>+</sup>/NADH; redox reactions, including FDH-conversion of formic acid into CO<sub>2</sub> and ADH-reduction of a ketone (e.g. 2-heptanone) into S-2-heptanol (abstract; page 361, ¶1). Orlich also teaches the reaction media of water (page 361, ¶1).

GROGER teaches conversion of a substrate, including poorly water-soluble ketones, into their corresponding (S)-alcohols by the action of ADH, FDH, and NADH recycling. Groger teaches substrate concentrations between 10 and 200 mM and reaction temperature of 30 °C. Groger further teaches reacting in water/aqueous solvent and beneficially teaching reacting with water:n-heptane (abstract, schemes 1 and 2). Groger also teaches that organic solvent positively affects solubility of organic substrate, but adversely affects enzyme activity. Furthermore, Groger teaches reacting in a purely aqueous media (scheme 2, aqueous phase); optimizing the water/aqueous composition components (percentage solvent in water), optimizing FDH activity of the reaction (e.g. Table S.I.1), and increasing the concentration of solute/substrate.

It would have been obvious to have modified Groger to a purely aqueous system, because Groger teaches that aqueous systems and providing solute at or above the solubility limit is known (e.g. scheme 2). This constructively teaches that solute is made available to the aqueous phase to the extent of its solubility limit in the respective solvent. One would have been motivated to use pure aqueous media, because Groger teaches that the reaction in aqueous media and that enzyme activity increases with increasing water proportion, wherein decreasing amounts of organic solvent provide increasing enzyme activity, with pure water having the highest enzyme activity. Additionally, the instant claims (e.g. claim 48) include aqueous:organic phase partitions of the reaction mixture. One would have had a reasonable expectation of success, because success depends upon the mere contacting of the components in the manner taught by Groger with the mere optimization of concentrations of components (see below) and especially in the absence of objective evidence to the contrary.

To the extent that Bomannus/Yamamoto/Sjoberg/Orlich/Groger may be silent with respect to the teachings of the specific ranges, concentrations, and/or temperatures of the instantly claimed invention, absent evidence to the contrary, it would have been *prima facie* obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. proportions/concentrations or reagents, temperature, reaction times, etc.), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition/methods with the composition/methods of the prior art, the burden is on

applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and “as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar  
Examiner, Art Unit 1651

/Michael G. Wityshyn/  
Supervisory Patent Examiner  
Art Unit 1651